IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: ZOSTAVAX (ZOSTER VACCINE LIVE) PRODUCTS LIABILITY LITIGATION	:	MDL NO. 2848
THIS DOCUMENT RELATES TO:	:	
JOHN DESTEFANO	:	
	:	CIVIL ACTION NO. 18-20070
v.	:	
MERCK & CO., INC., et al.	:	

MEMORANDUM IN SUPPORT OF PRETRIAL ORDERS NOS. 363 AND 364

Bartle, J. July 6, 2021

Plaintiff John Destefano, a citizen of Florida, brings this action against defendants Merck & Co., Inc. and Merck Sharp & Dohme Corp. (together, "Merck").[1] He claims that Zostavax, Merck's vaccine intended to reduce the risk of shingles, caused him to develop shingles. This is one of over 1,950 actions coordinated or consolidated for pretrial proceedings before the undersigned as a part of Multidistrict Litigation ("MDL") No. 2848. It is one of six Group A Bellwether Trial Pool Cases selected by the parties to proceed through case-specific discovery and dispositive motion practice in accordance with the procedure and schedule set forth in Pretrial Order ("PTO") No.

1. The parties stipulated to dismiss a third defendant, McKesson Corporation.

82, as amended by PTO Nos. 313, 346, 354 and 361. Before the court is the motion of Merck for summary judgment pursuant to Rule 56 of the Federal Rules of Civil Procedure on the ground that plaintiff has not produced an expert on causation. The court also has before it a subsequent cross-motion of plaintiff for dismissal with prejudice under Rule 41(a)(2).

I

Under Rule 56 of the Federal Rules of Civil Procedure, summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); see also Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). A factual dispute is genuine if the evidence is such that a reasonable factfinder could return a verdict for the non-moving party. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247-48 (1986). A factual dispute is material if it might affect the outcome of the suit under governing law. Id. at 248.

We view the facts and draw all inferences in favor of the non-moving party. See In re Flat Glass Antitrust Litig., 385 F.3d 350, 357 (3d Cir. 2004). "The mere existence of a scintilla of evidence in support of the [non-moving party]'s position will be insufficient; there must be evidence on which the jury could reasonably find for [the non-moving party]." See Anderson, 477 U.S. at 252. "The plaintiff must present affirmative

evidence in order to defeat a properly supported motion for summary judgment." Id. at 257. If a party fails to properly support an assertion of fact or fails to properly address another party's assertion of fact, the court may consider the fact undisputed for purposes of summary judgment. Fed. R. Civ. P. 56(e).

II

As noted above, plaintiff has not filed a response to Merck's motion for summary judgment. The court, therefore, considers the following facts undisputed. See Fed. R. Civ. P. 56(e)(2). It does so for purposes of this motion only.

In 2008, in accordance with guidelines from the Centers for Disease Control, plaintiff's primary care physician recommended plaintiff receive Zostavax — Merck's vaccine approved by the Food and Drug Administration for reducing the risk of shingles. Plaintiff's primary care physician typically informed patients before ordering Zostavax that the vaccine reduced the risk of getting shingles by 50%. He understood that shingles cases that developed in patients despite receiving Zostavax tended to be milder.

Plaintiff obtained the Zostavax vaccine from a pharmacy and brought it to the office of his primary care physician in Ormando Beach, Florida for administration. A nurse in the office administered it to him on March 21, 2008. The vaccine was accompanied by a package insert entitled "Highlights of Prescribing

Information." Section 5.4 of the insert stated that protection from shingles four years after receiving Zostavax was "unknown" and the need for revaccination was "not defined." Section 5.4 stated further that vaccination with Zostavax "may not result in protection of all vaccine recipients." Table 3 of the package insert listed Zostavax's efficacy at reducing the incidence of shingles among clinical trial participants. It provided that Zostavax's efficacy rate at reducing the risk of shingles among participants overall was 51%. Plaintiff's primary care physician was familiar with the information in the package insert.

Plaintiff was 64 years old when he received the vaccine. Table 3 listed a 64% efficacy rate among Zostavax clinical trial participants who were 60 to 69 years old. Plaintiff did not read the package insert or any other instructions, labels, or warnings concerning Zostavax.

On July 2, 2016, eight years after receiving Zostavax, plaintiff was diagnosed with shingles at a MediQuick walk-in clinic in Palm Coast, Florida. He had a reddened and raised rash and complained of mild pain and itching. A physician's assistant described the general appearance of plaintiff's rash as "mild." He also classified plaintiff's distress as "mild" and noted plaintiff did not appear to be in a "great deal of pain."

On June 1, 2018, plaintiff commenced this action in a Florida state court. Defendants removed the action to the United

States District Court for the Middle District of Florida, after which it was transferred to this court as a part of MDL No. 2848. Plaintiff alleges that the shingles infection he had in 2016 was caused by his receipt of Zostavax in 2008. He brings strict product liability claims against Merck for defective design and failure to warn. He also asserts claims under a theory of negligence as well as claims sounding in contract for breach of the implied and express warranties. He seeks compensatory and punitive damages.[2]

As noted, this action was selected by the parties as one of the Group A Bellwether Trial Pool Cases. Trial of the first of these cases is presently scheduled to begin on January 18, 2022. Plaintiff was required to serve Merck expert reports on March 19, 2021 but has not to date designated an expert who will testify that the shingles infection he suffered in 2016 was caused by his receipt of Zostavax in 2008. Merck, as noted above, moves for summary judgment on the ground that plaintiff has not proffered an expert who will testify that his inoculation with Zostavax in 2008 caused the shingles infection he suffered in 2016.

Under Florida law, "[t]he elements of a cause of action in tort are: (1) a legal duty owed by defendant to plaintiff, (2)

2. Plaintiff agreed to voluntarily dismiss additional claims for unjust enrichment and for defective manufacturing under theories of strict product liability and negligence.

breach of that duty by defendant, (3) injury to plaintiff legally caused by defendant's breach, and (4) damages as a result of that injury." Estate of Rotell v. Kuehnle, 38 So. 3d 783, 788 (Fla. Dist. Ct. App. 2010). "The elements of a breach of contract action are: (1) a valid contract; (2) a material breach; and (3) damages." People's Tr. Ins. Co. v. Valentin, 305 So. 3d 324, 326 (Fla. Dist. Ct. App. 2020).

Expert testimony is required to prove causation in cases where a jury is asked to assess complex medical or scientific issues outside the scope of a layperson's knowledge. Small v. Amgen, Inc., 723 F. App'x 722, 726 (11th Cir. 2018); see also Shepard v. Barnard, 949 So. 2d 232, 233 (Fla. Dist. Ct. App. 2007). Whether Zostavax caused plaintiff's shingles is certainly a complex medical question outside the scope of knowledge of a layperson. Likewise, expert testimony as to whether plaintiff developed shingles because of Zostavax is critical in determining whether there was a breach of contract. As plaintiff has not proffered an expert to tie Zostavax to the onset of his shingles, the tort and contract claims he asserts premised on such injury fail as a matter of law.

Accordingly, the court will grant summary judgment in favor of defendants Merck & Co., Inc. and Merck Sharp & Dohme Corp. and against plaintiff John Destefano on all claims.

III

The court will deny as moot plaintiff's belated cross-motion to dismiss under Rule 41(a)(2). Plaintiff's motion was not filed until after defendants had filed and briefed their meritorious motion for summary judgment.